

Certificate of Analysis

Date
15.11.2012
Purchase Order No. / Date
BI121586 / 05.11.2012
Delivery Note No.
5224002053 000010
Export No. / Date
5204002484 000010 / 06.11.2012
Customer's Code No.
472257

N. of Packages: 3 DRUM/S

PAPAVERINE HYDROCHLORIDE
USP 35 EUR.PH.7 ED. JP XV

Code N.: 07480000

Lot N.: 12100703 Quantity Delivered: 75 KG

Manufacturing Date: 05.11.2012 Expiry Date: 04.11.2017

Analysis N.: 30000244884 Date 14.11.2012

Analytical Procedure: 148PAC-12

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:

12K27-B01


Director Técnico

Solubility:

Sparingly soluble in water and in chloroform; slightly soluble
in alcohol; practically insoluble in ether.

ANALYTICAL TESTS	RESULTS	SPECIFICATIONS	
		MIN	MAX
Description	Complies	White odorless crystalline powder	
IR Spectrum identification	Complies	Complies USP	
UV Spectrum Identification	Complies	Complies USP	
Chlorides identification	Positive	Positive	
Eur.Ph.Assay (on dried basis)	100.9 %	99.0	101.0 %
USP Assay (on dried basis)	99.7 %	98.5	100.5 %
Loss on drying	0.02 %		0.50 %
HPLC E.P.Imp.B(PAPAVERINOL)	< 0.05 %		0.10 %
HPLC E.P.Imp.C(DIHYDROPAPAV)	< 0.05 %		0.10 %

**RECORDATI**INDUSTRIA CHIMICA E FARMACEUTICA S.p.A.
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TEL. (39) 0248787.1MANUFACTURING SITE: CAMPOVERDE
VIA MEDIANA CISTERNA, 4
04011 CAMPOVERDE DI APRILIA (LT), ITALY
Tel. (39) 0692900010 - FAX (39) 0692902016

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		MIN	MAX
HPLC E.P.Imp.D(PAPAVERALD)	< 0.05 %	0.10	%
HPLC E.P.Imp.E(TETRAHYDROPAP)	< 0.05 %	0.10	%
HPLC E.P.Imp.F	< 0.05 %	0.10	%
HPLC Each other impurity	< 0.05 %	0.10	%
HPLC Total impurities	< 0.05 %	0.50	%
Sulphated ash	0.04 %	0.10	%
pH (2% in water)	3.3 -	3.0	4.0 -
Clarity of water solution	Clear	Clear	
Colour of water solution	Complies	< = 6th level EP	
Completeness of chloroform solut.	Complies	Complete	
Readily carbonisable sub.(USP/JP)	Complies	Complies with the reference	
Org.res.solv.Methanol	< 32 ppm	100	ppm
Org.res.solv.Dimethylcarbonate	< 10 ppm	500	ppm

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ANALYTICAL TESTS	RESULTS	SPECIFICATIONS	
		MIN	MAX
Particle size D(10%)	37 μm	10	50 μm
Particle size D(50%)	83 μm	20	100 μm
Particle size D(90%)	145 μm	100	400 μm
Bulk density Loose	0.60 gr/ml	0.60	0.80 gr/ml
Bulk density Tapped	0.76 gr/ml	0.70	0.90 gr/ml

HPLC E.P. IMP.A (NOSCAPINE): Not applicable to our process

This batch has been manufactured, packaged and tested in accordance with
EU GMP Guideline Volume 4 Part II (ICHQ7).

QUALITY CONTROL MANAGER

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